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NOTE

From:	Presidency
To:	Delegations
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Subject:	Supplementary Protection Certificates (SPCs) Proposal for a Regulation on the Supplementary Protection Certificates for medicinal products (recast) - Partial revised text

In view of the Council Working Party on Intellectual Property on 5 December 2025, delegations will find in the Annex a partial revised Presidency text on a number of articles of the above-mentioned proposal.

Changes compared to the Commission proposal (doc. 8894/23) are highlighted in **bold underlined** or in ~~strikethrough~~. Changes compared to the previous revised Presidency text (doc. 14639/25) are indicated in grey shade and ~~double strikethrough~~.

This partial revised text is to be read in conjunction with the partial revised text on the proposal for a Regulation on the unitary SPCs (doc. 16178/2025), the stock taking paper set out in document 16248/25 and the note describing the functioning of the rotation mechanism for the designation of the rapporteur and the co-rapporteurs set out in WK 16641/2025.

2023/0130 (COD)

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on the supplementary protection certificate for medicinal products (recast)

Partial revised Presidency text

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down rules on the supplementary protection certificate ('certificate') for medicinal products protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(2) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;

(3) ‘basic patent’ means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(4) ‘application for an extension of the duration’ means an application for an extension of the duration of the certificate pursuant to Article 13(3) of this Regulation and Article 36 of Regulation (EC) No 1901/2006 [1];

(5) ‘maker’ means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out.

(6) ‘national application’ means an application for a certificate made before a competent national authority pursuant to Article 9;

(7) ‘centralised application’ means an application ~~made before~~ **lodged pursuant to Article 20 with** the **managing** ~~O~~**o**ffice [**referred to in Article 21b**] with a view to the grant of certificates, for the product identified in the application, in the designated Member States;

(8) ‘centralised application for an extension of the duration’ means an application **lodged pursuant to Article 20 with the managing office [referred to in Article 21b]** for an extension of the duration of the certificate pursuant to Article 30 of this Regulation and Article 36 of Regulation (EC) No 1901/2006;

(9) ‘designated Member State’ means a Member State for which a certificate is sought under the centralised examination procedure laid down in Chapter III, as identified in a centralised application ~~for a certificate~~;

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[1] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1) OJ L 378, 27.12.2006, p. 1.

(10) ‘European patent’ means a patent granted by the European Patent Office (EPO) under the rules and procedures laid down in the European Patent Convention (‘EPC’)[2];

(11) ‘unitary patent’ means a European patent which benefits from unitary effect ~~in those Member States participating in the enhanced cooperation laid down in~~ **pursuant to** Regulation (EU) No 1257/2012;

(12) ‘competent national authority’ means the national authority that is competent, in a given Member State, for the grant of certificates and for the rejection of applications for certificates, as referred to in Article 9(1) **and Article 32(2)**.

Chapter II
National applications for a certificate

Article 3

Conditions for obtaining a certificate

1. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application, all of the following conditions are fulfilled:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

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[2] Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000

2. By way of derogation from paragraph 1, a certificate shall not be granted under this Chapter, in a Member State, on the basis of a national application where the requirements of Article 20(1) are fulfilled for the filing of a centralised application in which that Member State would be designated.

3. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for that product may be issued to each of those holders, where they are not economically linked.

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Article 4

Scope of the protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

Article 5

Effects of the certificate

1. The certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

2. By way of derogation from paragraph 1, the certificate shall not confer protection against certain acts which would otherwise require the consent of the certificate holder, if all of the following conditions are met:

   (a) the acts comprise any of the following:

      (i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries;

(ii) any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export;

(iii) the making, no earlier than 6 months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate;

(iv) any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than 6 months before the expiry of the certificate.

(b) the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) in the Member State in which that making is to take place, and informs the certificate holder, of the information referred to in paragraph 5 no later than 3 months before the start date of the making in that Member State, or no later than 3 months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier;

(c) if the information referred to in paragraph 5 of this Article changes, the maker notifies the authority referred to in Article 9(1) and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex II, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 9 of this Article and, if applicable, with Article 12(2).

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3. Paragraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the Union merely for the purpose of repackaging, re-exporting or storing.

4. The information provided to the certificate holder for the purposes of paragraph 2, points (b) and (c), shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

5. For the purposes of paragraph 2, point (b), the maker shall provide all of the following information:

   (a) the name and address of the maker;

   (b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

   (c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

   (d) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making;

   (e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

6. For the purposes of notification to the authority under paragraph 2, points (b) and (c), the maker shall use the standard form for notification set out in Annex III.

7. Failure to provide the information referred to in paragraph 5, point (e), with regard to a third country shall only affect exports to that third country, and those exports shall not benefit from the exception laid down in paragraph 2.

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8. The maker shall ensure that medicinal products made pursuant to paragraph 2, point (a) (i), do not bear an active unique identifier within the meaning of Delegated Regulation (EU) 2016/161.

9. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker that performs acts falling under paragraph 2, point (a), is fully informed and aware of all of the following:

(a) that those acts are subject to paragraph 2;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(i), or the placing on the market of the product, or the medicinal product containing that product, referred to in paragraph 2, point (a)(iii), could infringe the certificate referred to in that paragraph where, and for as long as, that certificate applies.

10. Paragraph 2 shall apply to certificates that are applied for on or after 1 July 2019.

Paragraph 2 shall also apply to certificates that have been applied for before 1 July 2019 and that take effect on or after that date. Paragraph 2 shall only apply to such certificates from 2 July 2022.

Paragraph 2 shall not apply to certificates that have taken effect before 1 July 2019.

Article 6

Entitlement to the certificate

1. The certificate shall be granted to the holder of the basic patent or to the successor in title of that holder.

2. [Notwithstanding paragraph 1, where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, a certificate for that product shall not be granted to the holder of the basic patent without the consent of that third party].

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Article 7

Application for a certificate

1. The application for a certificate shall be lodged **by the holder of the basic patent** within 6 months of the date on which the authorisation referred to in Article 3(1), point (b), to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within 6 months of the date on which the patent is granted.

3. The application for an extension of the duration may be lodged at the same time when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1), point (d), or Article 8(2), respectively, are fulfilled.

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than 2 years before the expiry of the certificate.

Article 8

Content of the application for a certificate

1. The application for a certificate shall contain the following:

   (a) a request for the grant of a certificate, stating in particular:

      (i) the name**,** ~~and~~ address**, seat or principal place of business** of the **holder of the basic patent (“**applicant**”)**;

      (ii) if the applicant has appointed a representative, the name and address of that representative;

      (iii) the number of the basic patent and the title of the invention;

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(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3 (1), point (b)**,** and, if this authorisation is not the first authorisation for placing the product on the market in the Union, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(1), point (b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 35 of Regulation (EU) 2019/6;

(c) where the authorisation referred to in point (b) is not the first authorisation for placing the product on the market as a medicinal product in the Union, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication or, in the absence of such a notice, any other document proving that the authorisation has been issued, the date on which it was issued and the identity of the product authorised;

(ca) [**where a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, the consent of that party that a certificate for that product shall be granted to the holder of the basic patent**]**;**

(d) where the application for a certificate for a medicinal product includes ~~a request~~ **an application** for an extension of the duration:

(i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

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1a. **A centralised application in accordance with Chapter 3 shall, in addition to the information referred to in paragraph 1, contain the designation of the Member States in which certificates are sought.**

2. Where an application for a certificate is pending, an application for an extension of the duration in accordance with Article 7(3) shall include the particulars referred to in paragraph 1, point (d), of this Article and a reference to the application for a certificate already filed.

3. The application for an extension of the duration of a certificate already granted shall contain the particulars referred to in paragraph 1, point (d), and a copy of the certificate already granted.

4. Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

Articles 9 to 12 (will be addressed later)

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Union, reduced by a period of 5 years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed 5 years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 of this Article shall be extended by 6 months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of that Article may be extended only once.

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Article 14

Expiry of the certificate

The certificate shall lapse in any of the following events:

(a) at the end of the period provided for in Article 13;

(b) if the certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market in accordance with Directive 2001/83/EC or Regulation (EU) 2019/6.

For the purposes of point (d), the authority referred to in Article 9(1) may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Article 15

Invalidity of the certificate

1. The certificate shall be invalid in any of the following events:

(a) the certificate was granted contrary to Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent, or before a competent court of a Member State.

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Article 16

Revocation of an extension of the duration of a certificate ~~for a medicinal product~~

1. The extension of the duration may be revoked if it was granted contrary to Article 36 of Regulation (EC) No 1901/2006.

2. Any person may submit an application for revocation of the extension of the duration granted under this Chapter to the body responsible under national law for the revocation of the corresponding basic patent**, or before a competent court of a Member State**.

Article 17

Notification of lapse or invalidity

1. If the certificate lapses in accordance with Article 14, points (b), (c) or (d), or is invalid in accordance with Article 15, the authority referred to in Article 9(1) shall publish notification thereof.

2. If the extension of the duration is revoked in accordance with Article 16, the authority referred to in Article 9(1) shall publish notification thereof.

Article 18

Appeals

1. The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Article 15(2) and Article 16(2) taken under this Chapter shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Union, contained in the application for a certificate as provided for in Article 8, is incorrect.

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Articles 19

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates.

2. Notwithstanding paragraph 1, the procedure for opposition to the grant of a certificate shall be excluded.

Chapter III
Centralised procedure for certificates

Article 20

~~Scope of the c~~Centralised applications

1. Where the basic patent is a European patent, including a unitary patent, and the authorisation to place the product on the market has been granted through the centralised procedure under Regulation (EC) No 726/2004 or Regulation (EU) 2019/6, the procedure in this Chapter shall apply.

2. ~~When~~ **Where** the conditions under paragraph 1 are met, the filing of national applications **under Chapter II** shall be prohibited, in respect of the same product, in those Member States in which ~~that~~ **the** basic patent **referred to in paragraph 1** is in force.

3. A centralised application shall be lodged with the ~~European Union Intellectual Property Office established by Article 2 of Regulation (EU) 2017/1001 ('the Office')~~ **managing office referred to in Article 21b**.

4. Articles 1 to 7 and 13 to 18 shall apply to centralised applications.

5. The centralised application shall be lodged by using a specific application form **and shall contain the information referred to in Article 8(1) and 8(1a)**.

   The Commission is empowered to adopt implementing acts laying down rules on the application form to be used to lodge a centralised application. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.

Article 21

Content of the centralised application

(deleted)

~~The centralised application shall contain the following:~~

~~(a) designation of the Member States in which certificates are sought under the centralised procedure;~~ *(moved to new paragraph (1a) of Article 8)*

~~(b) the information referred to in Article 8(1).~~ *(moved to Article 20(5))*

(new) ***Article 21a***

Network of competent national authorities[3]

1. Competent national authorities shall cooperate within a network of competent national authorities ("network") that examines centralised applications and applications for extensions of the duration for the purpose of preparing a recommendation[4] **on the grant of national certificates or on the rejection of the application in accordance with Article 32 or on the grant or rejection of an extension of the duration, in accordance with Article 33. In case of combined applications referred to in Article 39, the network shall also perform the tasks set out in Regulation [COM(2023) 222].**

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[3] It suggested to clarify in a recital that only one single network is established for both the unitary SPC proposals and the recast proposals and that this network convenes in different constellations depending on whether it assesses a unitary SPC application, or a centralised or combined application:
"Competent national authorities should cooperate in a single network to conduct the examination procedures under this Regulation and the USPC Regulation. Participation in the network should be voluntary. For centralised and combined applications, the examination within the network should be conducted by all competent national authorities participating in the network. In case of USPC applications, only competent national authorities of the Member States in which the basic patent has unitary effect should take part in the examination procedure in accordance with Article 17(1) of the USPC proposal. ***To coordinate the work, a rapporteur and two co-rapporteurs should be appointed to make a first assessment of the application and draft a corresponding recommendation. The examining members of the network may provide comments to that recommendation. On that basis, the rapporteur and the co-rapporteurs will prepare the final recommendation which allows to take into account the views of all examining members****."*

[4] To streamline the text, a definition of "recommendation" could be inserted in Article 2.

2. **All competent national authorities shall be entitled to participate in the network. Competent national authorities shall notify the managing office referred to in Article 21b of their participation in the network.**

3. **Each competent national authority shall be part of the network upon the notification under paragraph 2 and shall perform the tasks conferred upon it pursuant to this Regulation in respect of applications filed after said notification.**

4. **Competent national authorities shall notify the managing office of any changes regarding their participation in the network, including the termination of such participation. Changes to the participation shall take effect [6 months] after the receipt of such a notification. Competent national authorities shall complete any tasks that are pending at the moment of the change in participation.**

5. **Competent national authorities shall ensure that examiners performing tasks within the network possess the required qualification in the relevant technical field or in law. They shall be impartial in the exercise of their duties and shall declare any actual or perceived conflict of interest.**

6. **The managing office shall produce a yearly report on the network's work, including on the involvement of each competent national authority.**

7. **The Commission is empowered to adopt implementing acts laying down the rules of procedure of the network. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.**

(new) ***Article 21b***

Managing office

The [EPO/EUIPO] shall act as the managing office. It shall provide procedural support to the network by performing, in particular, the following administrative tasks relating to centralised applications and related applications for extensions of duration established under this Chapter:

(a) **maintaining and publishing a list of competent national authorities participating in the network;**

(b) **receiving and publishing centralised applications, as well as applications for extensions of duration of related certificates, and transmitting applications to the network;**

(c) **verifying that the application fee [referred to in Article 34(1)] has been paid and informing the rapporteur and co-rapporteurs of the payment;**

(d) **transmitting to the network the draft recommendation prepared by the rapporteur and co-rapporteurs in accordance with Article 25b(2), as well as any comments or statements of disagreement regarding the draft recommendation;**

(e) **establishing and maintaining the register and database;**

(f) **transmitting communications between the rapporteur, co-rapporteurs or the network and the applicants, certificate holders and third parties;**

(g) **collecting and distributing fees.**

In cases of combined applications referred to in Article 39, the managing office shall also perform the tasks set out in [Article 9b of] Regulation [COM(2023) 222].

(new) ***Article 21c***

Rapporteur and co-rapporteurs

1. **For each application, the managing office shall designate from the network one competent national authority as rapporteur and two as co-rapporteurs based on an alphabetical rotation mechanism that is subject to the requirement that at least one of the co-rapporteurs are competent national authorities not making use of the exemption set out in Article 10(5).** *(second part of the sentence takes over former Article 21d(1))*

2. **In case of combined applications, the rapporteur and one co-rapporteur shall be from Member States in which the basic patent has unitary effect.** *(former Article 21d (2))*

3. **The Commission shall adopt implementing acts to determine the modus of operation of ~~criteria to be applied in~~ the rotation mechanism, ~~to~~ ensureing a fair distribution of workload among national offices. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.** *(former footnote on Article 21d(1)*

(new) ***Article 21e***
(former Article 23)

Publication of ~~the centralised~~ application~~s~~

The managing office shall publish ~~If the~~ centralised application**s** ~~complies with Article 22, or if an,~~ application**s** for an extension of the duration of certificates **and combined applications as referred to in Article 39** ~~complies with Article 33(2), the Office shall publish the application,~~ without undue delay, in the Register **and upon publication shall transmit them to the network**.

Article 22

~~Examination of the~~ Admissibility of ~~a centralised~~ application~~s~~

1. ~~The Office~~ **Once the managing office has confirmed that the application fee [referred to in Article 34(1)] has been paid, the rapporteur and co-rapporteurs** shall ~~examine~~ **assess** the following:

   (a) whether the ~~centralised~~ application ~~complies with Article 21~~ **contains the information set out in paragraphs (1) and (1a) of Article 8 as regards centralised applications or in Article 33(2) as regards related applications for an extension of the duration of certificates**; **and**

   (b) whether the ~~centralised~~ application complies with Article 7~~;~~

   ~~(c) whether the application fee referred to in Article 34(1) has been paid within the prescribed period~~.

2. Where **the rapporteur and co-rapporteurs find that** the ~~centralised~~ application does not satisfy the requirements referred to in paragraph 1, ~~the Office shall request~~ the applicant **shall be given the opportunity** to take the measures necessary to satisfy those requirements~~, and shall set a deadline for such compliance~~ **within [one month]**.

3. ~~Where the fee referred to in paragraph 1, point (c), has not been paid or has not been paid in full, the Office shall inform the applicant accordingly.~~

4. ~~If the applicant does not satisfy the requirements referred to in paragraph 1 within the deadline referred to in paragraph 2, the Office shall reject the application.~~

Article 23
(to reflect the sequence in the procedure,
Article 23 has been placed – as new Article 21e – before Article 22)

Article 24

Examination of the centralised application

(deleted / replaced by new Articles 25a -25d)

Article 25

Observations by third parties

1. Any natural or legal person may submit written observations to the **managing** ~~O~~**o**ffice ~~concerning the eligibility for supplementary protection of~~ **on whether the application and** the product to which ~~the application~~ **it** relates **comply with Articles 3(1), 3(3) and 6(2)** in one or more of the **designated** Member States ~~designated therein~~.

2. A natural or legal person that has submitted the written observations in accordance with paragraph 1 shall not be a party to the proceedings.

3. Third party observations shall be submitted within **[**~~3~~ **two]** months after publication of the centralised application in the Register.

4. Any observations by a third party shall be submitted in writing in one of the official languages of the Union[5] and state the grounds on which they are based.

5. **The managing office shall notify the applicant of** ~~A~~**a**ny observations by a third party ~~shall be notified to the applicant~~ **without undue delay**. The applicant may comment on the observations within ~~a time limit set by the Office~~ **[two] months from the expiry of the**

[5] Language regime to clarify once the choice of the managing office has been made.

deadline referred to in paragraph 1 or one month from the receipt of the observations, whichever is later.

6. **The managing office shall, without undue delay, transmit to the network any third party observations and any comments from the applicant received in accordance with paragraph 5.**

(new) ***Article 25a***[6]

General principles of the examination procedure

1. **All competent national authorities participating in the network shall take part in the examination procedure in accordance with Articles 25b to 25d.**

2. **The examination procedure shall generally be conducted in writing. However, plenary meetings of the network, to be held online, shall be convened by the managing office for the purpose of discussing cases referred to in Article 25c or at the request of the rapporteur at any stage of the procedure.**

3. **The network shall endeavour to reach consensus when examining the applications.**

4. **The Commission is empowered to adopt implementing acts laying down the rules of procedure regarding the examination of applications by the network, including on plenary meetings and majority requirements for cases when no consensus can be reached. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 56.**

(new) ***Article 25b***

Examination by the network

1. **The rapporteur and co-rapporteurs shall, within [three] months of the publication of the application in the register, or in case third party observations have been submitted, within [three] months after the receipt of any related comments of the**

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[6] Suggested new Articles 25a, 25b, 25c and 25d replace Articles 23, 27, 28 of the initial Commission proposal.

applicant [submitted in accordance with Article 25(6)], prepare a draft recommendation in respect of each designated Member State to either:

(a) grant a certificate, where the application and the product to which it relates comply with the requirements set out in this Regulation; or

(b) reject the application, where the application or the product to which it relates does not comply with the requirements set out in this Regulation.

When preparing the draft recommendation, they shall consider any third party observations submitted and any related comments received from the applicant.

2. The managing office shall transmit the draft recommendation to the network. Any member of the network may, within [two] months of the transmission of the draft recommendation, submit comments or a reasoned statement of disagreement to the managing office. The managing office shall, without undue delay, transmit to the network any comments and any statements of disagreement received.

3. If no statements of disagreement are received within the time limit referred to in paragraph 3, the recommendation shall be considered approved by the network and the managing office shall transmit the recommendation to the competent national authority of each designated Member State, for processing in accordance with Article 32.

(*new*) ***Article 25c***

Procedure for disagreement

1. Where one or more statements of disagreements have been submitted in accordance with Article 25b(3), the rapporteur and the co-rapporteurs may revise the draft recommendation based on the statements. Otherwise, they shall provide reasons for not following the statements of disagreement.

2. The managing office shall transmit the revised draft recommendation or the reasons for not following the statements of disagreement to the network.

3. If no further statements of disagreement are submitted or supported by a majority of the members of the network within [one month] [two months] from the transmission

under paragraph 2, the recommendation shall be considered approved by the network and the managing office shall transmit the recommendation to the competent national authorities of the designated Member States for processing in accordance with Article 32.

4. If a majority of the members of the network submit or support further statements of disagreement within [one month] [two months] from the transmission under paragraph 2, the rapporteur and co-rapporteurs shall refer the case for discussion in a plenary meeting, following which the managing office shall transmit the recommendation as approved by the network to the competent national authority of each designated Member State for processing in accordance with Article 32.

(*new*) ***Article 25d***

Consultation of the applicant and right to be heard

1. The rapporteur and co-rapporteurs may, at any stage of the procedure, invite the applicant to submit comments within a set time limit. Any comments received shall be transmitted to the network. The applicant may request oral proceedings in accordance with Article 44.

2. The rapporteur and the co-rapporteurs shall, before transmitting to the network any recommendation to reject the application, invite the applicant to submit comments within [2] months. Any comments received shall be transmitted to the network.

3. Before any decision under Article 32 is taken that may adversely affect the applicant, the applicant shall be given the opportunity to be heard.

Article 26

Opposition

(deleted)

Articles 27 – 31

(deleted / replaced by new Articles 21a, 21b, and 25a-25d)

Article 32

~~National implementation of a centralised examination opinion~~
Grant of a certificate or rejection of the application in designated Member States

1. ~~After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, t~~**T**he **managing** ~~O~~**o**ffice shall transmit the ~~examination opinion~~ **recommendation** and its translations to the competent national authority of each designated Member State.

1a. Member States can inform the managing office if, by way of derogation, no translation of the recommendations is required into their national languages. The derogation shall continue to apply until the Member State informs otherwise.

2. ~~In respect of a centralised application, where a positive examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall grant a certificate in accordance with applicable national rules and procedures.~~ **The competent national authority of each designated Member State shall decide to:**

(a) grant the certificate, where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation;

(b) reject the application, where the application for a certificate or the product to which it relates do not meet the conditions laid down in this Regulation.

When deciding whether to grant the certificate or reject the application, the competent national authorities shall take utmost consideration of the recommendation of the network.

3. ~~By way of derogation from paragraph 2, a Member State may decide not to grant a certificate, where material circumstances, in that Member State, have changed since the filing of the centralised application in respect of one or more of the conditions laid down in Article 15(1), points (b) or (c), or Article 14, first paragraph, point (d). In such a case that Member State shall reject the application insofar as that Member State is concerned.~~

4. A certificate granted by a competent national authority under this Article shall be subject to Articles 4, 5, 11 and 12 to 19, and to the applicable national legislation.

5. ~~Where a negative examination opinion has been issued for one or more designated Member State, the competent national authority of each of those Member States shall issue a rejection decision according to its applicable national rules and procedures.~~

Article 33

Centralised application for an extension of the duration of certificates

1. Where certificates for a given medicinal product have been granted through the centralised procedure, their holder may request an extension of the duration of those certificates by filing a centralised application for an extension of the duration of those certificates with the **managing** ~~O~~**o**ffice. That centralised application shall specify ~~the designation of~~ the Member States for which the extension is requested.

2. ~~The centralised application for an extension of the duration of certificates shall be filed~~ Article 7(3) and (4), Article 8(1), point (d), **Article 8(1a),** Article 8(2)~~,~~ **and** (3)~~ and (4)~~ **shall apply *mutatis mutandis* to a centralised application for ~~an~~the extension of the duration of certificates**.

3. Articles 10, 11 and 17 shall apply~~, whereby references to 'the authority referred to in Article 9(1)' shall be understood as references to the office~~.

4. ~~Third parties may also submit observations in respect of a centralised application for an extension of the duration of certificates.~~

Articles 34 to 38 (will be addressed later)

Article 39

Combined applications

1. A centralised application may ~~also~~ include a request for the grant of a unitary certificate, as defined in Regulation [COM(2023) 222][7] ('combined application').

2. The combined application shall undergo a single ~~centralised~~ examination procedure**, according to the rules set out in this Regulation and Regulation [COM(2023) 222]**~~, as well as a single opposition or appeal procedure, where it has been filed against an opinion or decision in respect of both the centralised application and the unitary certificate application~~.

3. The Member States for which the basic patent has unitary effect shall not be designated in the combined application for the parallel grant of national certificates. Any designation, in the combined application, of a Member State for which the basic patent has unitary effect shall be disregarded for the purpose of the examination of the combined application.

Article 40 (to be addressed later)

Article 41

Languages *(to be discussed later)*

1. All documents and information sent to the Office in respect of the procedures under this Regulation shall be in one of the official languages of the Union.

2. For the tasks conferred on the Office under this Regulation, the languages of the Office shall be all the official languages of the Union in accordance with Council Regulation No 1[8].

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[7] Regulation of the European Parliament and of the Council concerning the unitary supplementary protection certificate for medicinal products [COM(2023) 222].

[8] Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

Article 42

Communications to the managing ~~O~~office

1. **All** ~~Communications~~ **communications in procedures under this Chapter shall be** addressed to the **managing** ~~O~~**o**ffice **and** ~~may~~ **shall** be effected by electronic means. **The managing office shall forward the communications to the rapporteur, co-rapporteur or network, as appropriate.** ~~The Executive Director shall determine to what extent and under which technical conditions those communications may be submitted electronically~~.

2. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the rules on ~~the means of communication, including~~ the electronic means of communication to be used by the parties ~~to proceedings before~~ **for communications addressed to** the **managing** ~~O~~**o**ffice and the forms to be made available by the **managing** ~~O~~**o**ffice.

Articles 43 (to be addressed later)

Article 44

Oral proceedings

1. **Notwithstanding Article 25a(2),** ~~I~~**i**f the ~~Office~~ **rapporteur** considers that oral proceedings would be expedient, they shall be held either at the instance of the ~~Office~~ **rapporteur** or at the request of ~~any party to the proceedings~~ **the applicant**.

2. Oral proceedings ~~before an examination panel or opposition panel~~ **shall be held before the rapporteur and the co-rapporteurs, with at least one month notice of summons unless the applicant agrees to a shorter period. Oral proceedings shall be held online and shall** not be public. **The outcome of the oral proceedings shall be relayed to the network.**

3. ~~Oral proceedings before the Boards of Appeal, including delivery of the decision and, as the case may be, of a revised opinion, shall be public, unless the Boards of Appeal decide otherwise in cases where admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings.~~

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4. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for oral proceedings**,** **including on electronic means to be used and the summons to the oral proceedings**.

Article 45

Taking of evidence

1. ~~In any proceedings before the Office, t~~**T**he means of giving or obtaining evidence shall include the following:

   (a) hearing the ~~parties~~ **applicant**;

   (b) requests for information;

   (c) the production of documents and items of evidence;

   (d) hearing witnesses;

   (e) opinions by experts;

   (f) statements in writing sworn or affirmed or having a similar effect under the law of the State in which the statement is drawn up.

2. ~~The relevant panel may commission one of its members to examine the evidence adduced.~~

3. If the ~~Office or the relevant panel~~ **rapporteur** considers it necessary ~~for a party~~ **that the applicant**, **a** witness or **an** expert ~~to~~ give evidence orally, ~~it shall issue a summons to~~ **the managing office at the request of the rapporteur shall summon** the person concerned to ~~appear before it~~ **oral proceedings as referred to in Article 44**. The period of notice provided in such summons shall be at least 1 month, unless the~~y~~ **summoned person** agree**s** to a shorter period.

4. The ~~parties~~ **applicant** shall be informed of the hearing of a witness or expert ~~before the Office. They~~ **and** shall have the right to be present and to put questions to the witness or expert.

5. ~~The Executive Director shall determine the amounts of expenses to be paid, including advances, as regards the costs of taking of evidence as referred to in this Article.~~

6. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for the taking of evidence**, including on costs of taking of evidence**.

Article 46

Notification

1. The **managing** ~~O~~**o**ffice shall, as a matter of course, notify those concerned ~~of decisions, including opinions, summonses and~~ of any notice or other communication from which a time limit is reckoned, or of which those concerned are to be notified under other provisions of this Chapter ~~or of acts adopted pursuant to this Chapter, or of which notification has been ordered by the Executive Director~~.

2. Notification ~~may~~ **shall** be effected by ~~different means, including~~ electronic means. ~~The details regarding electronic means shall be determined by the Executive Director.~~

3. ~~Where notification is to be effected by public notice, the Executive Director shall determine how the public notice is to be given and shall fix the beginning of the 1-month period on the expiry of which the document shall be deemed to have been notified.~~

4. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for notification.

Article 47

Time limits

1. Time limits shall be laid down in terms of full years, months, weeks or days. Calculation shall start on the day following the day on which the relevant event occurred. The duration of time limits shall be no less than 1 month and no more than 6 months.

2. The ~~Executive Director~~ **managing office** shall determine, before the commencement of each calendar year, the days on which the **managing** ~~O~~**o**ffice is not open for receipt of ~~documents~~ **communications in accordance with Article 42** ~~or on which ordinary post is not delivered in the locality in which the Office is located~~.

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3. The ~~Executive Director~~ **managing office** shall determine the duration of the period of interruption ~~in the case of a general interruption in the delivery of post in the Member State where the Office is located or,~~ in the case of an ~~actual~~ interruption of the **managing** ~~O~~**o**ffice's ~~connection to admitted~~ electronic means of communication.

4. If an exceptional occurrence, such as a natural disaster ~~or strike~~, interrupts or interferes with proper communication from the parties to the proceedings to the **managing** ~~O~~**o**ffice or vice-versa, the ~~Executive Director~~ **managing office** may determine that for parties to the proceedings having their residence or registered office in the Member State concerned or who have appointed a representative with a place of business in the Member State concerned all time limits that otherwise would expire on or after the date of commencement of such occurrence, as determined by the ~~Executive Director~~ **managing office**, shall extend until a date to be determined by the ~~Executive Director~~ **managing office**. When determining that date, the ~~Executive Director~~ **managing office** shall assess when the exceptional occurrence comes to an end. If the occurrence affects the seat of the **managing** ~~O~~**o**ffice, such determination of the ~~Executive Director~~ **managing office** shall specify that it applies in respect of all parties to the proceedings.

5. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by specifying the details regarding the calculation and duration of time limits.

Article 48

Correction of errors and manifest oversights

1. The ~~Office~~ **network** shall correct any linguistic errors or errors of transcription and manifest oversights in its ~~decisions~~ **recommendations**~~, including opinions, or technical errors in publishing information in the Register,~~ of its own motion or at the request of ~~a party~~ **the applicant**.

1a. Linguistic errors or errors of transcription and manifest oversights in the decision of a competent national authority taken according to Article 32, shall be corrected in accordance with national law.

1b. The managing office shall correct linguistic errors or errors of transcription or manifest oversights in an entry in the Register where they originate from the network's recommendation or the decision of a competent national authority taken according to Article 32. The managing office shall correct such errors upon receipt of information from the network or competent national authority concerned that a correction has been made in accordance with, respectively, paragraph 1 or 1a.

2. Where the **managing** ~~O~~**o**ffice has made an entry in the Register ~~or taken a decision~~ which contains an obvious error attributable to the **managing** office, it shall ensure that the entry is cancelled ~~the decision is revoked~~. The cancellation of the entry in the Register ~~or the revocation of the decision~~ shall be effected within 1 year of the date on which the entry was made in the Register ~~or that decision was taken~~, after consultation with the ~~parties to the proceedings~~ **applicant**.

3. The **managing** ~~O~~**o**ffice shall keep records of any such corrections or cancellations **and shall publish them in the register**.

4. ~~Corrections and cancellations shall be published by the Office.~~ *(integrated into paragraph 3)*

Article 49

Restitutio in integrum

1. ~~The~~ **Where the** applicant ~~or any other party to~~ **in** proceedings ~~before the Office~~ under this Chapter~~, who~~, in spite of all due care required by the circumstances having been taken, was unable to comply with a time limit ~~vis-à-vis the Office~~**, he** shall, upon application, have his rights re-established if the obstacle to compliance has the direct consequence, by virtue of the provisions of this Chapter, of causing the loss of any right or means of redress.

2. The application for re-establishment shall be filed **with the managing office** in writing within 2 months of the removal of the obstacle to compliance with the time limit. ~~The omitted act shall be completed within this period. The application~~ **and** shall only be admissible within the year immediately following the expiry of the unobserved time limit.

3. The application for re-establishment shall state the grounds on which it is based and shall set out the facts on which it relies. It shall not be deemed to be filed until the fee for re-

establishment of rights has been paid. **The omitted act shall be completed within the relevant period for filing the request according to paragraph 2.**

4. The ~~SPC Division, or where applicable the Boards of Appeal,~~ **rapporteur and the co-rapporteur** shall ~~decide upon~~ **assess** the application **and include that assessment in the draft recommendation.**

5. This Article shall not be applicable to the time limits referred to in paragraph 2 of this Article~~, or in Article 26(1) and (3)~~.

Article 50

Interruption of proceedings

1. Proceedings ~~before the Office~~ under this Chapter shall be interrupted:

   (a) in the event of the death or legal incapacity of the applicant or of the person authorised by national law to act on behalf of the applicant. To the extent that that death or incapacity does not affect the authorisation of a representative appointed under Article 38, proceedings shall be interrupted only on application by such representative;

   (b) in the event of the applicant being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings ~~before the Office~~;

   (c) in the event of the death or legal incapacity of the representative of the applicant, or of that representative being prevented, for legal reasons resulting from action taken against his property, from continuing the proceedings ~~before the Office~~.

2. Proceedings ~~before the Office~~ **under this Chapter** shall be resumed as soon as the identity of the person authorised to continue them has been established.

3. The Commission is empowered to adopt delegated acts in accordance with Article 55 to supplement this Regulation by setting out the detailed arrangements for the resumption of proceedings ~~before the Office~~ **under this Chapter**.

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Article 51

Costs

(deleted)

Article 52

Enforcement of decisions fixing the amount of costs

(deleted)

Articles 53 (to be addressed later)

Article 54

Transitional provisions

This Regulation shall apply to certificates granted in accordance with the national legislation of Czechia, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia prior to their respective date of accession **to the Union**.

Article 58

Transitional provisions for pending applications

Article 20(2) shall not apply to national applications for certificates that are pending before competent national authorities on the xxxxxx [OP – please insert the date of application of this Regulation] and that meet the conditions under Article 20(1).

Articles 59 and 60 (to be addressed later)

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